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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Re application of:** Gladwin *et al.*

**Application No.** 10/563,682

**Filed:** January 6, 2006

**Confirmation No.** (unknown)

**For:** USE OF NITRITE SALTS FOR THE  
TREATMENT OF CARDIOVASCULAR  
CONDITIONS

**Examiner:**

**Art Unit:**

**Attorney Reference No.** 4239-67618-05

**CERTIFICATE OF MAILING**

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Attorney or Agent  
for Applicant(s)

Tanya M. Harding, Ph.D.

Date Mailed May 3, 2006

**INFORMATION DISCLOSURE STATEMENT  
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Listed on the accompanying form PTO-1449 and enclosed herewith are several English-language and/or non-English-language documents. Applicants respectfully request that these documents be listed as references cited on the issued patent.

Copies of United States patents and United States published patent applications do not have to be provided to the Patent Office (37 C.F.R. 1.98(a)(2)(ii)). Copies of unpublished U.S. applications do not have to be provided, as long as the application is available on PAIR, as this requirement of 37 C.F.R. § 1.98(a)(2)(iii) has been waived by the United States Patent and Trademark Office pursuant to the Official Gazette Notice on October 19, 2004 (1287 OG 163). Applicant will provide copies of such patents or applications upon request.

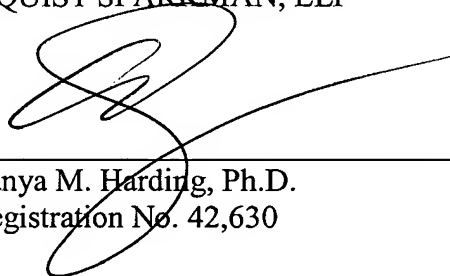
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The filing of this IDS shall not be construed to be an admission that the information cited in the statement is, or is considered to be, prior art or otherwise material to patentability as defined in 37 C.F.R. §1.56.

Respectfully submitted,

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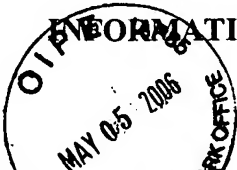
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### U.S. PATENT DOCUMENTS

Copies of U.S. Patent documents do not need to be provided, unless requested by the Patent and Trademark Office. For patents, provide the patent number and the issue date. For published U.S. applications, provide the publication number and the publication date. For unpublished pending patent applications, provide the application number and the filing date.

Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		5,108,754	04/28/1992	Wilburn
		5,177,208	01/05/1993	Wilburn
		5,648,101	07/15/1997	Tawashi
		5,770,645	06/23/1998	Stamler <i>et al.</i>
		5,885,621	03/23/1999	Head <i>et al.</i>
		5,912,019	06/15/1999	Singh
		6,057,367	05/02/2000	Stamler <i>et al.</i>
		6,087,479	07/11/2000	Stamler <i>et al.</i>
		6,103,275	08/15/2000	Seitz <i>et al.</i>
		6,314,956	11/13/2001	Stamler <i>et al.</i>
		6,471,978	10/29/2002	Stamler <i>et al.</i>
		6,472,390	10/29/2002	Stamler <i>et al.</i>
		2002/0090401	07/11/02	Tucker <i>et al.</i>
		2005/0036949	02/17/2005	Tucker <i>et al.</i>
		2005/0142218	06/30/2005	Tucker <i>et al.</i>

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### FOREIGN PATENT DOCUMENTS

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee
		EP	1336602	08/20/2003	
		WO	1994/22499	10/13/1994	
		WO	1995/12394	05/11/1995	
		WO	2000/53193	09/14/2000	
		WO	2001/89572	11/29/2001	
		WO	2002/17881	03/07/2002	
		WO	2002/17898	03/07/2002	
		WO	2003/032928	04/24/2003	
		WO	2005/004884	01/20/2005	

Examiner's Initials*	Cite No. (optional)	OTHER DOCUMENTS
		ABMAN <i>et al.</i> , "Inhaled ethyl nitrite gas for persistent pulmonary hypertension in infants," <i>Lancet</i> , 360:2076-2077 (2002) (Including Author's Reply)
		ASLAN <i>et al.</i> , "Oxygen radical inhibition of nitric-oxide dependent vascular function in sickle cell disease," <i>PNAS</i> , 98:15215-15220 (2001)
		BHUGRA <i>et al.</i> , "A study of nitrogen oxide containing vasodilators on guinea pig trachea, a nonvascular smooth muscle," <i>Indian J. Pharmac.</i> , 17:92-97 (1985)
		BIAN <i>et al.</i> , "Nitric Oxide (NO) - Biogenesis, regulation, and relevance to human diseases," <i>Frontiers in Bioscience</i> , 8:d264-278 (2003)
		BJÖRNE <i>et al.</i> , "Nitrite in saliva increases gastric mucosal blood flow and mucus thickness," <i>J. Clin. Invest.</i> , 113:106-114 (2004)

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Examiner's Initials*	Cite No. (optional)	OTHER DOCUMENTS
		CANNON <i>et al.</i> , "Effects of inhaled nitric oxide on regional blood flow are consistent with intravascular nitric oxide delivery," <i>J. Clin. Invest.</i> , 108:279-287 (2001)
		COKIC <i>et al.</i> , "Hydroxyurea induces fetal hemoglobin by the nitric oxide-dependent activation of soluble guanylyl cyclase," <i>J. Clin. Invest.</i> , 111:231-239 (2003)
		CHANNON, "Tetrahydrobiopterin: Regulator of Endothelial Nitric Oxide Synthase in Vascular Disease," <i>Trends Cardiovasc. Med.</i> , 14(8):323-327 (2004)
		COSBY <i>et al.</i> , "Nitrite reduction to nitric oxide by deoxyhemoglobin vasodilates the human circulation," <i>Nature Medicine</i> , 9(12):1498-1505 (2003), plus Supplementary matter (5 pages)
		CRAWFORD <i>et al.</i> , "Vasoactivity of S-nitrosohemoglobin: role of oxygen, heme and NO oxidation states," <i>Blood</i> , 101:4408-4415 (2003)
		DEEM <i>et al.</i> , "Effects of S-Nitrosation of Hemoglobin on Hypoxic Pulmonary Vasoconstriction and Nitric Oxide Flux," <i>Am. J. Respir. Crit. Care Med.</i> , 163:1164-1170 (2001)
		DEEM <i>et al.</i> , "Effects of S-Nitrosation and Cross-Linking of Hemoglobin on Hypoxic Pulmonary Vasoconstriction in Isolated Rat Lungs," <i>Circ. Res.</i> , 91:626-632 (2002)
		DEMONCHEAUX <i>et al.</i> , "Circulating nitrite anions are a directly acting vasodilator and are donors for nitric oxide," <i>Clin. Sci.</i> , 102:77-83 (2002)
		DOYLE <i>et al.</i> , "Kinetics and Mechanism of the Oxidation of Human Deoxyhemoglobin by Nitrites," <i>J. Biol. Chem.</i> , 256(23):12393-12398 (1981)
		DURANSKI <i>et al.</i> , "Cytoprotective effects of nitrite during in vivo ischemia-reperfusion of the heart and liver," <i>J. Clin. Invest.</i> 115(5):1232-1240 (2005)
		FOX-ROBICHAUD <i>et al.</i> , "Inhaled NO as a Viable Antiadhesive Therapy for Ischemia/Reperfusion Injury of Distal Microvascular Beds," <i>J. Clin. Invest.</i> , 101:2497-2505 (1998)

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Examiner's Initials*	Cite No. (optional)	OTHER DOCUMENTS
		GIANETTI <i>et al.</i> , "Supplemental nitric oxide and its effect of myocardial injury and function in patients undergoing cardiac surgery with extracorporeal circulation," <i>J. Thorac. Cardiovasc. Surg.</i> , 127:44-50 (2004)
		GLADWIN <i>et al.</i> , "Inhaled nitric oxide augments nitric oxide transport on sickle cell hemoglobin without affecting oxygen affinity," <i>J Clin. Invest.</i> , 104:937-945 (1999)
		GLADWIN <i>et al.</i> , "The Acute Chest Syndrome in Sickle Cell Disease, Possible Role of Nitric Oxide in Its Pathophysiology and Treatment," <i>Am. J. Respir. Crit. Care Med.</i> , 159:1368-1376 (1999)
		GLADWIN <i>et al.</i> , "Pathogenesis and treatment of acute chest syndrome of sickle-cell anaemia," <i>Lancet</i> , 355:1476-1478 (2000)
		GLADWIN <i>et al.</i> , "Relative role of heme nitrosylation and $\beta$ -cysteine 93 nitrosation in the transport and metabolism of nitric oxide by hemoglobin in the human circulation," <i>PNAS</i> , 97:9943-9948 (2000)
		GLADWIN <i>et al.</i> , "Role of circulating nitrite and S-nitrosohemoglobin in the regulation of regional blood flow in humans," <i>PNAS</i> , 97:11482-11487 (2000)
		GLADWIN <i>et al.</i> , "Nitric oxide therapy in sickle cell disease," <i>Seminars in Hematology</i> , 38:333-342 (2001)
		GLADWIN <i>et al.</i> , "Nitric Oxide Transport on Sickle Cell Hemoglobin: Where Does it Bind?" <i>Free Radic. Res.</i> , 35:175-180 (2001)
		GLADWIN <i>et al.</i> , "Nitric oxide donor properties of hydroxyurea in patients with sickle cell disease," <i>British J. Haematology</i> , 116:436-444 (2002)
		GLADWIN <i>et al.</i> , "S-Nitrosohemoglobin Is Unstable in the Reductive Erythrocyte Environment and Lacks O <sub>2</sub> /NO-Linked Allosteric Function," <i>J. Biol. Chem.</i> , 277:27818-27828 (2002)
		GLADWIN <i>et al.</i> , "Divergent Nitric Oxide Bioavailability in Men and Women With Sickle Cell Disease," <i>Circulation</i> , 107:271-278 (2003)

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		GLADWIN <i>et al.</i> , "Nitric oxide's reactions with hemoglobin: a view through the SNO-storm," <i>Nature Medicine</i> , 9:496-500 (2003)
		GLADWIN, "Haldane, hot dogs, halitosis, and hypoxic vasodilation: the emerging biology of the nitrite anion," <i>J. Clin. Invest.</i> , 113:19-21 (2004)
		GLADWIN <i>et al.</i> , "The emerging biology of the nitrite anion," <i>Nature Chem. Biol.</i> , 1(6):308-314 (2005)
		GRUETTER <i>et al.</i> , "Methylene blue inhibits coronary arterial relaxation and guanylate cyclase activation by nitroglycerin, sodium nitrite, and amyl nitrite," <i>Can. J. Physiol. Pharmacol.</i> , 59:150-156 (1981)
		GUO <i>et al.</i> , "Endothelial Preserving Actions of a Nitric Oxide Donor in Carotid Arterial Intimal Injury," <i>Meth. Find. Exp. Clin. Pharmacol.</i> , 16(5):347-354 (1994)
		HAN <i>et al.</i> , "Nitric oxide reaction with red blood cells and hemoglobin under heterogeneous conditions," <i>PNAS</i> , 99:7763-7768 (2002)
		HEAD <i>et al.</i> , "Low Concentrations of Nitric Oxide Increase Oxygen Affinity of Sick Erythrocytes In Vitro and In Vivo," <i>J. Clin. Invest.</i> , 100(5):1193-1198 (1997)
		HEROLD and RÖCK, "Reactions of Deoxy-, Oxy-, And Methemoglobin with Nitrogen Monoxide: Mechanistic Studies of the S-Nitrosothiol Formation Under Different Mixing Conditions," <i>J. Biol. Chem.</i> , 278:6623-6634 (2003)
		HOBBS <i>et al.</i> , "Haemoglobin: NO transporter, NO inactivator or None of the above?" <i>Trends Pharmacol. Sci.</i> , 23:406-411 (2002)
		HRINCZENKO <i>et al.</i> , "Effect of nitric oxide and nitric oxide donors on red blood cell oxygen transport," <i>Br. J. Haematol.</i> , 110:412-419 (2000)
		HUNTER <i>et al.</i> , "Inhaled nebulized nitrite is a hypoxia-sensitive NO-dependent selective pulmonary vasodilator," <i>Nat. Med.</i> , 10(10):1122-1227 (2004)
		IGNARRO <i>et al.</i> , "Endothelium-derived relaxing factor produced and released from artery and vein is nitric oxide," <i>PNAS</i> , 84:9265-9269 (1987)

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		JISON and GLADWIN, "Hemolytic Anemia-associated Pulmonary Hypertension of Sickle Cell Disease and the Nitric Oxide/Arginine Pathway," <i>Am. J. Respir. Crit. Care Med.</i> , 168:3-4 (2003)
		JOSHI <i>et al.</i> , "Nitric oxide is consumed, rather than conserved, by reaction with oxyhemoglobin under physiological conditions," <i>PNAS</i> , 99(16):10341-10346 (2002)
		KING, "A role for nitric oxide in hydroxyurea-mediated fetal hemoglobin induction," <i>J. Clin. Invest.</i> , 111:171-172 (2003)
		KOHELET, "Nitric Oxide Inhalation and High Frequency Oscillatory Ventilation for Hypoxemic Respiratory Failure in Infants," <i>Israel Med. Assoc. J.</i> , 5:19-23 (2003)
		KOZLOV <i>et al.</i> , "Mechanisms of Vasodilation Induced by Nitrite Instillation in Intestinal Lumen: Possible Role of Hemoglobin," <i>Antioxid. Redox. Signal.</i> , 7:515-521 (2005)
		KUO <i>et al.</i> , "Nitrosation of cysteine and reduced glutathione by nitrite at physiological pH," <i>Frontiers in Bioscience</i> , 8:a62-69 (2003)
		LANCASTER, "Reaping of nitric oxide by sickle cell disease," <i>PNAS</i> , 99:552-553 (2002)
		LAUER <i>et al.</i> , "Plasma nitrite rather than nitrate reflects regional endothelial nitric oxide synthase activity but lacks intrinsic vasodilator action," <i>PNAS</i> , 98:12814-12819 (2001)
		LEFER, "Myocardial Protective Actions of Nitric Oxide Donors After Myocardial Ischemia and Reperfusion," <i>New Horizons</i> , 3(1):105-112 (1995)
		LEFER, "Nitrite therapy for protection against ischemia-reperfusion injury," <i>Am. J. Physiol. Renal Physiol.</i> , 290:F777-F778 (2005)
		LI <i>et al.</i> , "Characterization of the effects of oxygen on xanthine oxidase-mediated nitric oxide formation," <i>J. Biol. Chem.</i> , 279(17):16939-16946 (2004)
		LIAO, "Blood feud: Keeping hemoglobin from nixing NO," <i>Nature Medicine</i> , 8(12):1350-1351 (2002)

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		LUCHSINGER <i>et al.</i> , "Assessments of the chemistry and vasodilatory activity of nitrite with hemoglobin under physiologically relevant conditions," <i>J. Inorg. Biochem.</i> , 99:912-921 (2005)
		MATSUNAGA and FURCHGOTT, "Interactions of light and sodium nitrite in producing relaxation of rabbit aorta," <i>J. Pharmacol. Exp. Ther.</i> , 248(2):687-695 (1989)
		MCLEAN <i>et al.</i> , "Inducible expression of the kinin B <sub>1</sub> receptor in the endotoxemic heart: mechanisms of des-Arg <sup>9</sup> bradykinin-induced coronary vasodilation," <i>Br. J. Pharmacol.</i> , 128:275-282 (1999)
		MODIN <i>et al.</i> , "Nitrite-derived nitric oxide: a possible mediator of 'acidic-metabolic' vasodilation," <i>Acta. Physiol. Scand.</i> , 171:9-16 (2001)
		MOORE <i>et al.</i> , "Regional Cerebral Hyperperfusion and Nitric Oxide Pathway Dysregulation in Fabry Disease," <i>Circulation</i> , 104:1506-1512 (2001)
		MOYA <i>et al.</i> , "Inhaled ethyl nitrite gas for persistent pulmonary hypertension of the newborn," <i>Lancet</i> , 360:141-143 (2002)
		NAGABABU <i>et al.</i> , "Active Nitric Oxide Produced in the Red Cell under Hypoxic Conditions by Deoxyhemoglobin-mediated Nitrite Reduction," <i>J. Biol. Chem.</i> , 278(47):46349-46356 (2003)
		OKAMOTO <i>et al.</i> , "Nitrite-derived nitric oxide formation following ischemia-reperfusion injury in kidney," <i>Am. J. Physiol. Renal Physiol.</i> 288:F182-187 (2005)
		PARK <i>et al.</i> , "Combined Effects of Inhaled Nitric Oxide and a Recruitment Maneuver in Patients with Acute Respiratory Distress Syndrome," <i>Yonsei Med. J.</i> , 44(2):219-226 (2003)
		PI <i>et al.</i> , "Effects of adenosine on ischaemia-reperfusion injury associated with rat pancreas transplantation," <i>British J. Surgery</i> , 88:1366-1375 (2001)
		PLUTA <i>et al.</i> , "Nitrite Infusions to Prevent Delayed Cerebral Vasospasm in a Primate Model of Subarachnoid Hemorrhage," <i>JAMA</i> , 293:1477-1484 (2005)

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		PODEROSO <i>et al.</i> , "Nitric oxide regulates oxygen uptake and hydrogen peroxide release by the isolated beating rat heart," <i>Am. J. Physiol.</i> , 274 ( <i>Cell Physiol.</i> 43): C112-119 (1998)
		RASSAF <i>et al.</i> , "Evidence for in vivo transport of bioactive nitric oxide in human plasma," <i>J. Clin. Invest.</i> , 109:1241-1248 (2002)
		REITER <i>et al.</i> , "Cell-free hemoglobin limits nitric oxide bioavailability in sickle-cell disease," <i>Nature Medicine</i> , 8:1383-1389 (2002)
		REITER and GLADWIN, "An emerging role for nitric oxide in sickle cell disease vascular homeostasis and therapy," <i>Curr. Opin. Hematol.</i> , 10:99-107 (2003)
		SCHECHTER and GLADWIN, "Hemoglobin and the Paracrine and Endocrine Functions Of Nitric Oxide," <i>N. Engl. J. Med.</i> , 348(15):1483-1485 (2003)
		SCHECHTER <i>et al.</i> , "NO solutions?" <i>J. Clin. Invest.</i> , 109:1149-1151 (2002)
		SCHERMULY <i>et al.</i> , "Reversal of experimental pulmonary hypertension by PDGF inhibition," <i>J. Clin. Invest.</i> , 115:2811-2821 (2005)
		STUBBE <i>et al.</i> , "Inhaled nitric oxide reduces lung edema during fluid resuscitation in ovine acute lung injury," <i>Intens. Care Med.</i> , 29(10):1790-1797 (2003)
		SULLIVAN <i>et al.</i> , "Nitric oxide successfully used to treat acute chest syndrome of sickle cell disease in a young adolescent," <i>Crit. Care Med.</i> , 27:2563-2568 (1999)
		TIRAVANTI <i>et al.</i> , "Nitrosyl-Heme Complexes Are Formed in the Ischemic Heart," <i>J. Biol. Chem.</i> , 279(12):11065-11073 (2004)
		TSIKAS and FRÖLICH, "Is circulating nitrite a directly acting vasodilator?" <i>Clin. Sci.</i> , 103:107-110 (2002)
		TSUCHIYA <i>et al.</i> , "Malfunction of Vascular Control in Lifestyle-Related Diseases: Formation of Systemic Hemoglobin-Nitric Oxide Complexes (HbNO) From Dietary Nitrite," <i>J. Pharmacol. Sci.</i> , 96:395-400 (2004)

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		TSUCHIYA <i>et al.</i> , "Nitrite is an alternative source of NO in vivo," <i>Am. J. Physiol. Heart Circ. Physiol.</i> , 288:H2163-2170 (2005)
		TUCKER <i>et al.</i> , "Effect of nitric-oxide-generating system on microcirculatory blood flow in skin of patients with severe Raynaud's syndrome: a randomised trial," <i>Lancet</i> , 354:1670-1675 (1999)
		UGA <i>et al.</i> , "Nitric oxide inhalation therapy in very low-birthweight infants with hypoplastic lung due to oligohydramnios," <i>Pediatr. Int.</i> , 46:10-14 (2004)
		WAGNER <i>et al.</i> , "Nitric Oxide Inhalation in the Treatment of Right Ventricular Infarction," <i>Eur. Heart J.</i> , 23:326 Suppl. S P1717 (2002)
		WEBB <i>et al.</i> , "Inorganic nitrite: protector against ischaemia reperfusion injury in the heart," <i>Br. J. Pharmacol.</i> , 138 (Proceedings Supplement):20P (April 2003)
		WEBB <i>et al.</i> , "Reduction of nitrite to nitric oxide during ischemia protects against myocardial ischemia-reperfusion damage," <i>PNAS</i> , 101(37):13683-13688 (2004)
		WEYERBROCK <i>et al.</i> , "Selective opening of the blood-tumor barrier by a nitric oxide donor and long-term survival in rats with C6 gliomas," <i>J. Neurosurg.</i> , 99:728-737 (2003)
		WINK, "Ion implicated in blood pact," <i>Nature Medicine</i> , 9(12):1460-1461 (2003)
		WOLZT <i>et al.</i> , "Biochemical Characterization of S-Nitrosohemoglobin. Mechanisms Underlying Synthesis, NO release, and Biological Activity," <i>J. Biol. Chem.</i> , 274:28983-28990 (1999)
		XU <i>et al.</i> , "Effects of Iron Nitrosylation on Sick Cell Hemoglobin Solubility," <i>J. Biol. Chem.</i> , 277:36787-36792 (2002)
		YANG <i>et al.</i> , "Methodologies for the Sensitive and Specific Measurement of S-nitrosothiols, Iron-nitrosyls, and Nitrite in Biological Samples," <i>Free Radic. Res.</i> , 37:1-10 (2003)

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Attorney Docket Number	4239-67618-05
	Application Number	10/563,682
	Filing Date	January 6, 2006
	First Named Inventor	Gladwin
	Art Unit	
	Examiner Name	

Examiner's Initials*	Cite No. (optional)	OTHER DOCUMENTS
		ZUZAK <i>et al.</i> , "Imaging hemoglobin oxygen saturation in sickle cell disease patients using noninvasive visible reflectance hyperspectral techniques: effects of nitric oxide," <i>Am. J. Physiol. Heart Circ. Physiol.</i> , 285:H1183-H1189 (2003)
		Agency for Toxic Substances and Disease Registry, "Case Studies in Environmental Medicine (CSME): Nitrate/Nitrite Toxicity," Course SS3054, ATSDR Publication No. ATSDR-HE-CS-2002-0007, Revision Date: January 2001
		BBC News, <a href="http://www.bbc.co.uk/2/hi/health/516365.stm">www.bbc.co.uk/2/hi/health/516365.stm</a> , published 11/12/1999, printed 03/23/2004. "Gel improves circulation disorder."
		Boston.com, NEERGARD, "Sodium nitrite could be disease cure," <a href="http://www.boston.com/yourlife/health/diseases/articles/2005/09/05/sodium_nitrite_could...">www.boston.com/yourlife/health/diseases/articles/2005/09/05/sodium_nitrite_could...</a> printed 09/06/2005
		MACK <i>et al.</i> , "Sodium nitrite increases regional blood flow in patients with sickle cell disease," Poster displayed at least as early as April 12, 2005 at 28 <sup>th</sup> Annual Meeting of the National Sickle Cell Disease Program
		MACK <i>et al.</i> , "Sodium nitrite increases regional blood flow in patients with sickle cell disease," Abstract for poster displayed at least as early as April 12, 2005 at 28 <sup>th</sup> Annual Meeting of the National Sickle Cell Disease Program
		Six letters to the Editor, <i>N. Engl. J. Med.</i> , 349(4):402-405 (2003)
		The Merck Index, Eleventh Edition, "An encyclopedia of chemicals, drugs, and biologicals," page 1365 (1989)

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